

### **REMARKS**

The Final Office Action mailed February 22, 2010 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 1-60 are pending in this application. Claims 28-60 are withdrawn. No amendments are presented herein.

#### **Claim Rejections - 35 U.S.C. § 112**

Claims 1-27 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action alleges that "[t]he specification does not describe how the drag force provides substantially all of the energy for movement of the binding member." (Office Action, p. 2.) Additionally, the Office Action alleges that "it is unclear if the (sic) 'the movement' is the rotation of the binding member or the sliding of the needle." (Office Action, p. 2.) However, the Instant Application states the following:

Friction members 126 are configured for slidable engagement with stylet 106 between the retracted position and the extended position such that friction members 126 engage stylet 106 to create a drag force with stylet 106. It is envisioned that one or a plurality of friction members 126 may be employed.

*The drag force in conjunction with one of blocking members 116 and/or 117, cause binding member 105 to move to a binding position (FIG. 4). The force created by blocking members 116 and/or 117 acts in a direction opposite to the drag force. This causes a force couple, which moves binding member 105 to the binding position.*

As stylet 106 is released from engagement with a stylet communicating surface 123, binding member 105 and a retainer 114 move to the binding position. Rotation of binding member 105 is no longer opposed by engagement with stylet 106 at stylet communicating surface 123. Thus, binding member 105, with retainer 114, is subject to inclination into the

binding position. Rotation of binding member 105 causes binding surfaces 122 to frictionally engage stylet 106 to prevent movement thereof.

Blocking members 116 and/or 117 cause binding member 105 to move to the binding position as forces imposed on shield 101 cause relative movement thereof in either direction along longitudinal axis x. This maintains stylet 106 within shield 101 to avoid hazardous exposure to distal end 115. It is envisioned that stylet communicating surface 123 may include ribs, projections, cavities, etc. for engagement with stylet 106 or that a portion of stylet communicating surface 123 engages stylet 106.

(Instant Application, p. 12, ll. 8-30, emphasis added).

Accordingly, in one embodiment, the friction members 126 create the drag force. An equal and opposite force is exerted by the blocking member(s) 116, 117 *in accordance with Newton's third law of motion*<sup>1</sup> to create the force couple.<sup>2</sup> These forces cause the binding member 105 to move to the binding position. (See, Instant Application for example, FIG. 4.) Accordingly, the blocking member 116, 117 do not *provide energy* to the system, rather they block movement.

Additionally, blocking members 116, 117 are illustrated in the Instant Application, FIG. 5. They are part of bearing 102. The "[b]earing 102 may be monolithically formed" (p. 13, l. 7). Accordingly, the bearing *may* consist of one piece and be solid.<sup>3</sup> Such a bearing would tend to store

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<sup>1</sup> Newton's third law of motion states that "[w]henver a first body exerts a force  $F$  on a second body, the second body exerts a force  $-F$  on the first body.  $F$  and  $-F$  are equal in magnitude and opposite in direction." Newton's Laws of Motion. Wikipedia.org. [http://en.wikipedia.org/wiki/Newton's\\_laws\\_of\\_motion](http://en.wikipedia.org/wiki/Newton's_laws_of_motion) (accessed: March 10, 2010).

<sup>2</sup> A force couple (couple) is "a pair of equal, parallel forces acting in opposite directions and tending to produce rotation." Couple. Dictionary.com. *Dictionary.com Unabridged*. Random House, Inc. <http://dictionary.reference.com/browse/couple> (accessed: March 10, 2010).

<sup>3</sup> Monolithically. Dictionary.com. *Dictionary.com Unabridged*. Random House, Inc. <http://dictionary.reference.com/browse/monolithically> (accessed: March 10, 2010).

little or no energy and provide little or no energy back to the system during removal of the needle. Thus, if the blocking members provide little or no energy to the system and no other sources of energy are present in the system, then the drag force *must* provide substantially all of the energy for movement of the binding member. Even if the blocking member of the instant application stored energy, this energy would be imparted to the blocking member of the apparatus of the instant application by the drag forces.<sup>4</sup>

Accordingly, the only source of energy in the system is the drag force provided by friction with the needle. Thus, the Application, as originally filed does describe how the drag force provides substantially all of the energy for movement of the binding member.<sup>5</sup>

The Office Action alleges that “it is unclear if the (sic) ‘the movement’ is the rotation of the binding member or the sliding of the needle.” Applicants respectfully point out that the amendment from the previous Office Action refers to “providing . . . energy *for* movement.” The amendment does not simply state “the movement.” The claimed embodiment relates to an apparatus that uses energy from friction with the needle when it moves to provide energy *for* movement to cause rotational motion. Accordingly, the energy for movement is the energy that causes rotation.

Independent claim 1 recites, *inter alia*, “[movement of] the needle . . . create[s] a drag force . . . the drag force providing substantially all of the energy for movement *such that* the drag force and a blocking member cause rotation” (emphasis added). Accordingly, from claim 1 a person of ordinary skill in the art knows that, (1) the movement of the needle creates the drag force, (2) the drag force provides the energy *for* movement, and (3) the energy *for* movement is the energy from

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<sup>4</sup> Nothing in the instant application indicates that the embodiment discussed above has any other sources of energy for movement. Further, nothing indicates a stored energy device, such as a spring.

<sup>5</sup> Applicants note that other medical needle shield apparatus embodiments discussed in the specification may be configured such that the drag force provides substantially all of the energy for movement of the binding member. The example discussed above is only one illustrative embodiment. Accordingly, the claims should not be limited by this discussion. For example, a bearing that is not monolithically formed might be used in another example system, but still receive substantially all of the energy for movement of the binding member from drag force.

the drag force that *causes* rotation (“such that” connects the drag force and the rotation). Accordingly, the energy *for* movement ultimately comes *from* the movement of the needle and this energy is what ultimately *causes* rotation. Thus, Applicants believe that “energy for movement” is clear.

For the reasons discussed above, Applicants request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

### **Claim Rejections - 35 U.S.C. § 102**

Claims 1-13 and 15 -27 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over USP/N 5,697,907 to Gaba (hereinafter, “Gaba”). Applicants respectfully traverse this rejection.

Independent claim 1 recites, *inter alia*, a “binding member including at least one drag inducing member such that the at least one drag inducing member engages the needle during slidable receipt of the needle to create a drag force with the needle, the drag force providing substantially all of the energy for movement such that the drag force and a blocking member cause rotation of the binding member relative to a longitudinal axis of the needle such that the binding surfaces engage the needle to prevent slidable movement of the needle in the extended position of the shield, the binding member further including a needle communicating surface extending therefrom such that the needle communicating surface is engageable with the needle to prevent rotation of the binding member.”

The Office Action fails to specifically point out which features of Gaba allegedly constitute several features of independent claim 1. Upon careful review of Gaba, Applicants are unable to locate at least the feature of “the drag force providing *substantially all* of the energy for movement such that the drag force and a blocking member cause rotation of the binding member.” (Claim 1, emphasis added.)

Additionally, the Office Action alleges, “Applicant argues that Gaba does not teach a blocking member as claimed. There is nothing in the specification limiting what can be considered

a blocking member and the spring 352 prevents or blocks the binding member from rotating clockwise.” (Office Action, p. 4.)

Even assuming, *arguendo*, that a spring is a blocking member, claim 1 expressly states that “the drag force provid[es] *substantially all of the energy for movement* such that the drag force and a blocking member cause rotation of the binding member.” (Claim 1.) Conversely, Gaba expressly states that “[t]he *spring 352 shifts the retainer 348.*” (Gaba, col. 5:67 to col. 6:1, emphasis added.) Accordingly, even if there are drag forces in Gaba, a point which Applicants do not concede, it cannot be said that “the drag force provid[es] *substantially all of the energy for movement* such that the drag force and a blocking member cause rotation of the binding member” as recited in claim 1. Rather, in Gaba, the spring 352 provides the energy.

Additionally, the spring 352 is not a blocking member. As discussed above, the blocking members 116, 117 do not *provide energy* to the system, rather they block movement in a particular direction so as to direct a drag force. “[T]he force created by blocking members 116 and/or 117 *acts in a direction opposite to the drag force.*” (See Instant Application, p.12, lines 12-15, and FIG. 4, emphasis added). On the contrary, in Gaba, the spring 352 does not block movement in one direction such that frictional forces with the needle acting in the opposite direction can cause rotation. The spring 352 causes the motion. Further, Applicants reiterate the arguments from the July 7, 2009 and January 8, 2010 responses with respect to Gaba.

Accordingly, in view of the above, independent claim 1 is patentable over Gaba as Gaba does not show or describe each of the limitations thereof. Dependent claims 2-13 and 15-27 are patentable because they depend from a patentable independent claim, and also because they recite features not shown or described by the cited art. Therefore, Applicants request favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 102.

### **Claim Rejections - 35 U.S.C. § 103**

Claim 14 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Gaba in view of USPN 4,978,344 to Dombrowski et al. (hereinafter "Dombrowski"). Applicants respectfully traverse this rejection.

Without conceding the propriety of the asserted combination, or the assertions made in the Office Action with respect to the allegedly disclosed subject matter, Applicants submit that claim 14 depends from patentable independent claim 1, in view of the above, and is therefore patentable. Accordingly, Applicants request favorable reconsideration and withdrawal of this rejection under 35 U.S.C. § 103.

### **Conclusion**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicants of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

Applicants believe no fee is due with this submission. However, if a fee is due, please charge our Deposit Account No. 50-2191, under Order No. 101673.0057P4 from which the undersigned is authorized to draw.

Dated: March 22, 2010

Respectfully submitted,

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